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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/825,909 | 04/04/2001 | David L. Thompson | P-8999 | 3722 |

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MEDTRONIC, INC.
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EXAMINER

OROPEZA, FRANCES P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3762

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,909

Applicant(s)

THOMPSON ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/7/03 (Amendment) and 5/19/03 (RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 5/19/03 has been entered.

Response to Arguments

2. The Applicant's arguments filed 4/7/03 regarding the Feingold rejections have been fully considered and are convincing. The rejection of claims 1-2 and 4-5 under 35 U.S.C. 102(b) as being anticipated by Feingold (US 4871351) and the rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Feingold (US 4871351) in view of Amano et al. (US 5941837) are withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the preamble of claim 1, the Applicant claims a system for controlling the operations of the implanted device via an external

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device, but the body of the claim provides for the data collected by the external device/ sensor to be transmitted to the implanted device so the implanted device processor can control the delivery of therapy to the patient. The specification indicates the external medical devices (sensors) influence the operation of the implanted device (page 2, lines 26-28), but the Examiner is unable to find a teaching of the external device controlling the implanted device. Clarification is needed.

4. Claims 1-5 are rejected under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

The scope of claim 1 is indefinite because the preamble of the claim indicates the external device controls the operation of the implanted medical device and the body of the claim indicated the external device provides collected data to the implanted device and the implantable device processor controls the therapy provided by the implanted device.

Claim 1 is indefinite because it is not clear how the external device (sensor) controls the implanted medical device.

Claim Rejections - 35 USC § 102

5. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tockman et al. (US 5562707). Tockman et al. teach a method and apparatus to automatically optimized the pacing mode and pacing cycle parameters of an implantable stimulating device using and optimization sequence, read as providing a dynamic closed loop self monitoring system. The apparatus comprises a pacemaker (10), a micro-controller (32) an RF telemetry link (40), and external sensors/ monitors (42-50), including and oximeter (50). (figure 1;

col. 1 @ 8-15; col. 1 @ 66 – col. 2 @ 15; col. 3 @ 58-62; col. 3 @ 66 – col. 4 @ 24;
col. 5 @ 8 – col. 6 @ 59)

Claim Rejections - 35 USC § 103

6. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prochazka et al. (US 5562707) in view of Salo et al. (US 5487752).

Prochezka et al. discloses a wrist worn sensor (14) and controller (15) for providing functional electrical stimulation to an implanted muscle microstimulator (72) (figures 1 and 7; col. 6 @ 45-54). The IMD is a neuro stimulator. The external sensor is a wristwatch sensor, where the wrist position sensor (14) and distal portion of the glove (18A) provide a signal indicating wrist position (col. 5 @ 26-35). The medical data is the pressure of muscular stress as the wrist is flexed and extended.

As to the device being an implantable medical device, Prochazka et al. discloses an implantable medical device, an implanted muscle microstimulator (72) that uses radio frequency signals to transmit energy and commands to the microstimulator (figure 7; col. 6 @ 46-54). As noted in figure 8 – reference numeral 95, the connector pads are associated with electrodes or antenna/implant, hence the stimulator provides the stimulation pulses to the muscles using both contact pads and the implanted muscle microstimulator (72) (figure 7; col. 6 @ 46-54).

As to the microstimulator having processor capability, Prochazka et al. teach the microstimulator and external antenna might be in the form of the devices described by Schulman et al (US 5193540). The Schulman et al. device, discloses an implantable microstimulator with a circuit means including control electronics/ logic (16), read as a processor controlling the delivery of the therapy to the patient (abstract; figure 2; col. 4 @ 64 – col. 5 @ 10).

As to claim 5, the sensor disclosed by Prochazka et al. is a joint movement sensor. A joint movement sensor is a well known physiological sensing device used in the electrical stimulation art. Absent any teachings of criticality or unexpected results, merely change the type of sensor would be an obvious design choice.

As discussed in the previous four paragraphs, Prochazka et al. disclose the claimed invention except for the physiological data being transferred to the implanted medical device.

Salo et al. teach physiological monitoring using externally mounted sensors that monitor a physiological condition and transfers the physiological data signal to the sensor signal processor of the implanted device for the purpose of controlling the therapy provided by the implantable medical device. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the external sensor that monitors a physiological condition and transfers the physiological data signal to the implanted device in the Prochazka et al. system in order to simplify the external electronics of the monitoring system by eliminating the need for the external controller to produce a control signal (abstract; figure 4; col. 4 @ 37-60; col. 6 @ 37-44).

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tockman et al. (US 5540727) in view of Kopotic (US 6470199). As discussed in paragraph 5 of this action, Tockman et al. disclose the claimed invention except for the pulse oximeter being a sock.

Kopotic et al. teach oximeter positioning using a sock for the purpose of securing the oximeter in place in an environment (against the nail/ skin of the big toe) hostile to adhesive-based, spring-tension-based, and/or hook-and-loop-based securing systems. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a sock to

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secure the oximeter in the Tockman et al. system in order to avoid skin and tissue damage and to avoid misalignment of the emitter and detector of the oximeter leading to faulty oximeter reading and inaccurate determination of the pulse rate and blood oxygen saturation (col. 1 @ 19-24 and 34-52; col. 2 @ 30-42; col. 12 @ 55-56).

Claim Objections

8. Claims 1-5 are objected to because in claim 1, line 14 it appears "of dynamic" should be --dynamic--.

Statutory Basis

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

6/5/03

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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